

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
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JOHN KENDRUP et al.) Group Art Unit: (unassigned)
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Application No.: (unassigned)) Examiner: (unassigned)
)
Filed: March 29, 2001)
)
For: METHOD FOR PRODUCING A)
CONTROLLED-RELEASE)
COMPOSITION)

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned patent application, kindly enter the following amendment.

IN THE CLAIMS:

Kindly replace claims 3-16 and 19-22 as follows.

3. (Amended) A method according to claim 1, wherein the mean particle size of the pore-forming agent is 0.1-500 μm , preferably is 0.5-100 μm and the most preferably 1-25 μm .

4. (Amended) A method according to claim 1, wherein the pore-forming agent is selected from a group consisting of potassium salts, calcium salts, magnesium salts, amino acids, weak acids, carbohydrates, polymers with amino and/or acid functions or a composition wherein at least one of the components is selected from one of these groups.

5. (Amended) A method according to claim 1, wherein the pore-forming agent is potassium bitartrate, creatine, asparagine, glutamine, aspartic acid, glutamic acid, leucin, neroleucine, inosine, isoleucine, magnesium citrate, magnesium phosphate, magnesium carbonate, magnesium hydroxide, magnesium oxide or a composition wherein at least one component is selected from one of these substances.

6. (Amended) A method according to claim 1, wherein the pore-forming agent is chitosan and poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1.

7. (Amended) A method according to claim 1, wherein the water insoluble polymer is selected from one of the groups of cellulose esters, acrylic polymers, polyvinyl acetates, polyvinyl chlorides or a composition wherein at least one component is selected from one of the groups.

8. (Amended) A method according to claim 1, wherein the coating polymer is ethylcellulose, celluloseacetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylmethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylammonioethylmetacrylatechloride), a block- or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

9. (Amended) A method according to claim 1, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

10. (Amended) A method according to claim 1, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

11. (Amended) A method according to claim 1, wherein the solid core includes at least one drug selected from the group consisting of tranquilizers, antibiotics, hypnotics, antihypertensives, antianginas, analgesics, antiinflammatories, neuroleptics, antidiabetics, diuretics, anticholinergics, antihyperacidics or antiepileptics, ACE inhibitors β -receptor antagonists and agonists, anaesthetics, anorexians, antiarrhythmics, antidepressants, anticoagulants, antidiarrhoeics, antihistamines, antimalariels, antineoplastics, immunosuppressives, antiparkinsonians, antipsychotics, antiplatelets, diuretics, antihyperlipidics.

12. (Amended) A method according to claim 1, wherein the drug for the solid core is potassium chloride, theophylline, a theophylline salt, phenylpropanolamine, sodium salicylate, choline theophyllinate, paracetamol, carbidopa, levodopa, diltiazem, enalapril, verapamil, naproxen, pseudoephedrin, nicorandil, oxybutin, morphine, oxycodone or propranolol.

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13. (Amended) A method according to claim 1, wherein the aqueous dispersion includes at most 20%, preferably at most 10% and most preferably at most 5% by weight of organic solvent.

14. (Amended) A method according to claim 1, wherein the obtained coated cores are cured with heat or moisture.

15. (Amended) A method according to claim 1, wherein the pore-former in the coating suspension is stabilized with one or more ionic, non-ionic or polymer surfactants.

16. (Amended) A method according to claim 1, wherein the coating polymer is plasticized.

19. (Amended) Preparation according to claim 17, wherein the amount of the pore-forming agent is 40-95, preferable 50-90% and most preferably 55-88% by weight of the total weight of the dry coating.

20. (Amended) Preparation according to claim 17, wherein the polymer is ethylcellulose, cellulose-acetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylemethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylammonioethylmetacrylchloride), a block-or copolymer of the

polymers or a composition wherein at least one of the components is selected from these polymers.

21. (Amended) Preparation according to claim 17, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

22. (Amended) Preparation according to claim 17, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

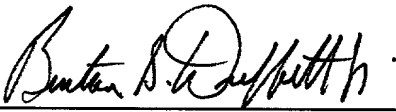
REMARKS

The present Amendment is intended to eliminate the use of multiple dependency.

The examination and allowance of the application are respectfully requested.

Respectfully submitted,

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Marked-up Claims 3-16 and 19-22

3. (Amended) A method according to [any one of the claims 1-2] claim 1, wherein the mean particle size of the pore-forming agent is 0.1-500 μm , preferably is 0.5-100 μm and the most preferably 1-25 μm .

4. (Amended) A method according to [any one of the claims 1-3] claim 1, wherein the pore-forming agent is selected from a group consisting of potassium salts, calcium salts, magnesium salts, amino acids, [week] weak acids, carbohydrates, polymers with amino and/or acid functions or a composition wherein at least one of the components is selected from one of these groups.

5. (Amended) A method according to [any one of the claims 1-4] claim 1, wherein the pore-forming agent is potassium bitartrate, creatine, asparagine, glutamine, aspartic acid, glutamic acid, leucin, neroleucine, inosine, isoleucine, magnesium citrate, magnesium phosphate, magnesium carbonate, magnesium hydroxide, magnesium oxide or a composition wherein at least one component is selected from one of these substances.

6. (Amended) A method according to [any one of the claims 1-5] claim 1, wherein the pore-forming agent is chitosan and poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) 1:2:1.

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Marked-up Claims 3-16 and 19-22

7. (Amended) A method according to [any of the claims 1-6] claim 1, wherein the water insoluble polymer is selected from one of the groups of cellulose esters, acrylic polymers, polyvinyl acetates, polyvinyl chlorides or a composition wherein at least one component is selected from one of the groups.

8. (Amended) A method according to [any one of the claims 1-7] claim 1, wherein the coating polymer is ethylcellulose, celluloseacetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylmethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylammonioethylmetacrylatechloride), a block- or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

9. (Amended) A method according to [any one of the claims 1-7] claim 1, wherein the coating polymer is a copolymer consisting of 50-100% by weight of polyvinyl chloride and 0-50% by weight of polyvinyl acetate.

10. (Amended) A method according to [any one of the claims 1-7] claim 1, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

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Marked-up Claims 3-16 and 19-22

11. (Amended) A method according to [any one of the claims 1-10] claim 1, wherein the solid core includes at least one drug selected from the group consisting of tranquilizers, antibiotics, hypnotics, antihypertensives, antianginas, analgesics, antiinflammatories, neuroleptics, antidiabetics, diuretics, anticholinergics, antihyperacids or antiepileptics, ACE inhibitors β -receptor antagonists and agonists, anaesthetics, anorexiant, antiarrhythmics, antidepressants, anticoagulants, antidiarrhoeics, antihistamines, antimalarials, antineoplastics, immunosuppressives, antiparkinsonians, antipsychotics, antiplatelets, diuretics, antihyperlipidics.

12. (Amended) A method according to [any one of the claims 1-11] claim 1, wherein the drug for the solid core is potassium chloride, theophylline, a theophylline salt, phenylpropanolamine, sodium salicylate, choline theophyllinate, paracetamol, carbidopa, levodopa, diltiazem, enalapril, verapamil, naproxen, pseudoephedrin, nicorandil, oxybutuin, morphine, oxycodone or propranolol.

13. (Amended) A method according to [any one of the claims 1-12] claim 1, wherein the aqueous dispersion includes at most 20%, preferably at most 10% and most preferably at most 5% by weight of organic solvent.

14. (Amended) A method according to [any one of the claims 1-12] claim 1, wherein the obtained coated cores are cured with heat or moisture.

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Marked-up Claims 3-16 and 19-22

15. (Amended) A method according to [any one of the claims 1-17] claim 1, wherein the pore-former in the coating suspension is stabilized with one or more ionic, non-ionic or polymer surfactants.
16. (Amended) A method according to [any one of the claims 1-18] claim 1, wherein the coating polymer is plasticized.
19. (Amended) Preparation according to [any one of the claims 17 or 18] claim 17, wherein the amount of the pore-forming agent is 40-95, preferable 50-90% and most preferably 55-88% by weight of the total weight of the dry coating.
20. (Amended) Preparation according to [any one of the claims 17-19] claim 17, wherein the polymer is ethylcellulose, cellulose-acetate, celluloseacetatebutyrate, celluloseacetatepropionate, nitrocellulose, polymethylemethacrylate, poly(ethylacrylate, methylmetacrylate), polyvinylacetate, polyvinylchloride, polyethylene, polyisobutylene, poly(ethylacrylate, methylmetacrylate, trimethylamoniethylmetacrylatchloride), a block-or copolymer of the polymers or a composition wherein at least one of the components is selected from these polymers.

Marked-up Claims 3-16 and 19-22

22. (Amended) Preparation according to [claims 17-19] claim 17, wherein the coating polymer is a copolymer consisting of 80-95% by weight of polyvinylchloride, 0,5-19% by weight of polyvinylacetate and 0,5-10% by weight of polyvinylalcohol.

Year	Total population		Population aged 15 years and over		Population aged 65 years and over		Population aged 75 years and over		Population aged 85 years and over		Population aged 95 years and over	
	Number	Density	Number	Density	Number	Density	Number	Density	Number	Density	Number	Density
1990	1 000 000	100	700 000	70	100 000	10	50 000	5	20 000	2	10 000	1
2000	1 100 000	110	750 000	75	110 000	11	55 000	5	22 000	2	11 000	1
2010	1 200 000	120	800 000	80	120 000	12	60 000	6	24 000	2	12 000	1
2020	1 300 000	130	850 000	85	130 000	13	65 000	6	26 000	2	13 000	1
2030	1 400 000	140	900 000	90	140 000	14	70 000	7	28 000	2	14 000	1
2040	1 500 000	150	950 000	95	150 000	15	75 000	7	30 000	3	15 000	1
2050	1 600 000	160	1 000 000	100	160 000	16	80 000	8	32 000	3	16 000	1
2060	1 700 000	170	1 050 000	105	170 000	17	85 000	8	34 000	3	17 000	1
2070	1 800 000	180	1 100 000	110	180 000	18	90 000	9	36 000	3	18 000	1
2080	1 900 000	190	1 150 000	115	190 000	19	95 000	9	38 000	3	19 000	1
2090	2 000 000	200	1 200 000	120	200 000	20	100 000	10	40 000	4	20 000	1
2100	2 100 000	210	1 250 000	125	210 000	21	105 000	10	42 000	4	21 000	1